

657—13.16(124,155A) Telepharmacy site—initial application.

13.16(1) *License application.* A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information identified in this rule.

13.16(2) *CSA registration application.* If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy license application and fee, the CSA registration application and fee as provided in rule 657—10.1(124).

13.16(3) *Identification of managing pharmacy.* The telepharmacy site application shall include identification of the managing pharmacy, including pharmacy name, license number, address, telephone number, pharmacist in charge, and a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site.

13.16(4) *Distance to nearest general pharmacy.* The telepharmacy site application shall identify the nearest licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed general pharmacy is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus, and services will be limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) *Written agreement.* The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

13.16(6) *Key personnel.* The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy and the telepharmacy site and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel. Telepharmacy technician identification shall also include a copy of the telepharmacy technician's current national certification or other verification of the telepharmacy technician's current national certification.

13.16(7) *Audiovisual technology.* A description of the audiovisual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. Requiring a verifying pharmacist to review and compare the electronic image of any new prescription with the data entry record of the prescription prior to authorizing the telepharmacy site's system to print a prescription label and prior to the telepharmacy technician's filling of the prescription at the telepharmacy site.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to the dispensing of the prescription at the telepharmacy site.

d. Ensuring that the telepharmacy site's system prevents a prescription from being sold and delivered to a patient before the verifying pharmacist has performed a final verification of the accuracy of the prescription and released the prescription for sale and delivery at the telepharmacy site.

13.16(8) *Request for distance waiver.* The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed

telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver or variance identified in 657—Chapter 34.

b. In addition to the requirements of 657—Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(3) That access to the nearest currently licensed general pharmacy that dispenses prescription drugs to outpatients is limited. A description of how the proposed telepharmacy site will improve patient access to pharmacy services shall be included.

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed general pharmacy, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public health.

(1) The director shall have the power to approve, modify, or veto the board's proposed decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

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